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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/077,048 | 02/14/2002 | Euljoon Park | A02P1016 | 1591 |
| 36802 | 7590 | 09/22/2004 | EXAMINER | |
| PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221 | | | EVANISKO, GEORGE ROBERT | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |
| DATE MAILED: 09/22/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/077,048

Applicant(s)

PARK ET AL.

Examiner

George R Evanisko

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date multiple.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 9/8/03 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance of EP 1295623, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 5-8, 12-16, and 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 2 and 5, line 6, the second occurrence of “on” should be deleted and “the comparative analysis” lacks antecedent basis. In addition, the claim is incomplete for omitting essential elements amounting to a gap in the structure for not providing an element to perform “the comparative analysis...”. It is unclear what element is performing the analysis. An element is needed to perform the analysis since the timing is “based on” the analysis.

In claim 6, “comparative analysis” lacks antecedent basis and makes the claim incomplete.

Art Unit: 3762

In claims 7 and 8, line 4, “detects a sleep apnea condition” is vague. Is this the same as the potential sleep apnea condition in claim 1 or a different condition (if it is the same, “the sleep apnea condition” should be used). In addition, in line 7, “on one” or more of the parameters is vague since claim 1 uses both parameters. It is suggested to delete “one or more of”. In the next to last line “a sleep apnea condition” is vague since it can not be determined if this is the same condition used in line 4 and/or claim 1.

In claim 12, line 8, “based on a comparative analysis” is vague and makes the claim incomplete. It is suggested to positively recite an element to perform the analysis.

In claim 13, “on one” or more of the parameters is vague.

In claim 14, the second occurrence of “on” should be deleted and “the comparative analysis” lacks antecedent basis.

In claim 15, “comparative analysis” makes the claim incomplete.

In claim 22, line 3, “a sleep apnea condition” is vague since it is used in claim 17. Is this the same condition or a different condition?

In claim 23, line 10, “a” should be deleted.

In claim 25, line 3, “a sleep apnea condition” is vague. Is this the same condition detected in claim 23 or a different condition?

In claim 26, the claim is incomplete for omitting essential structural relationship between elements. The means for generating is not connected to any other element in claim 23. In addition, in line 3, “a” sleep apnea condition is vague.

Art Unit: 3762

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 4, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourgeois et al (6126611). Bourgeois uses the activity sensor to turn on the system to detect apnea with the impedance sensor and therefore the circuitry is “based on” the activity and impedance sensor.

Claims 1-7, 9, and 12-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Bonnet (6574507). Bonnet uses impedance (column 4) and acceleration (column 4) to detect

Art Unit: 3762

when the patient is sleeping and has a potential apnea and incorporates by reference patent numbers 5622428, 5722996, and 5766228 which provide for different stimulation over different activity levels (rest, sleep, awake, exercise, etc.). In addition, Bonnet states that muscular and neurological stimulation of respiratory muscles can be used with the cardiac stimulation (columns 8 and 9). Also, for claim 12, the examiner has considered the first and second levels to be the same and therefore Bonnet meets the limitations of claim 12.

Claims 1, 2, 4, 5, 7, 9-13, 16, 17, 19, 21-23, 25, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Cho et al (6641542). Cho uses both impedance and acceleration to detect a sleep apnea condition and provides both cardiac stimulation and hypoglossal stimulation (column 10). In addition, for claim 12, the examiner has considered the first and second levels to be the same level.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 3762

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 6, 14, 15, 18, 20, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho. Cho discloses the claimed invention except for the activity sensor and metabolic sensor to indicate that the patient is sleeping or sleeping, resting, and exercising to deliver therapy based on the activity level. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sleep apnea prevention system as taught by Cho, with an activity sensor and metabolic sensor to indicate the patient is sleeping or sleeping, resting, and exercising to deliver therapy based on the activity level since it was known in the art that sleep apnea systems use an activity sensor and metabolic sensor to indicate the patient is sleeping or sleeping, resting, and exercising to provide a sensor system that uses a combination of conventional sensors and processing to accurately and easily determine the activity level of the patient to deliver appropriate therapy to the patient based on the activity level.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonnet.

Bonnet discloses the claimed invention except for the blood oxygen or carbon dioxide concentration sensors and activating therapy when the concentration is depressed or elevated, respectively. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apnea prevention system as taught by Bonnet, with a blood oxygen or carbon dioxide concentration sensor that activates therapy when the concentration is depressed or elevated since it was known in the art that apnea prevention systems use a blood oxygen or carbon dioxide concentration sensor that activates therapy when the concentration is

Art Unit: 3762

depressed or elevated to provide a conventional sensor with known processing of the sensor signal to easily determines if an apnea is occurring and trigger therapy to prevent the apnea.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, 5, 17, 19, and 23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of copending Application No. 10/247137 and claim 17 of copending application No. 10/077660. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application claims are broader and read on the narrower claims in the copending applications. In addition, to include a controller to process the sensors signals would be obvious to one having ordinary skill in the art at the time the invention was made since it was known in the art to use controllers to process signals in implantable devices to provide an automated, inexpensive system to quickly process the signals.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 3762

Allowable Subject Matter


Claim 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 703 308-2612. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

9/19/04

GRE
September 19, 2004